

Newborn Screening Quality Assurance Program

QUALITY CONTROL

MIDYEAR REPORT

Volume 17, No. 1

June 2006

INTRODUCTION

The Newborn Screening Quality Assurance Program (NSQAP), Centers for Disease Control and Prevention (CDC), distributed dried-blood-spot (DBS) quality control (QC) materials for thyroxine (T_4), thyroid-stimulating hormone (TSH), 17 α -hydroxyprogesterone (17-OHP), total galactose (Gal), phenylalanine (Phe), leucine (Leu), methionine (Met), tyrosine (Tyr), valine (Val), citrulline (Cit), and nine acylcarnitines (C3, C4, C5, C5DC, C6, C8, C10, C14, C16) to laboratories operating newborn screening programs and to manufacturers of screening test products. Included with each semiannual shipment of QC specimens were data-report forms to be completed and returned to CDC.

This midyear report contains a summary of the QC data submitted during the first half of 2006 by state, contract, and private laboratories in the United States; international participants; and manufacturers of screening test products.

----- QC DATA -----
see pages 4-25

QUALITY CONTROL MATERIALS

The QC specimen lots were provided as 6-month supplies of DBSs on filter paper. All DBS QC lots were prepared from whole blood of 55% hematocrit with lysed red blood cells. The QC materials were enriched with predetermined quantities of the selected analytes and dispensed in 100 μ L aliquots on Whatman Inc. (Fairfield, NJ) Grade 903 filter paper.

A QC shipment for T_4 , TSH, or 17-OHP consisted of blood-spot materials from three lots per analyte, with each lot containing a different concentration of analyte. A QC shipment for Gal, Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines consisted of blood-spot cards from four different lots.

The QC materials were supplied for use as external controls in quantities sufficient to maintain continuity and transcend changes in production lots of routinely used method- or kit-control materials. The external QC materials were intended to supplement the participants' method- or kit-control materials at periodic intervals and to allow participants to monitor the long-term stability of their assays. The QC materials should not be used as routine daily QCs.

PARTICIPANTS' RESULTS

For this midyear report, we compiled the data that each participant reported from five analytic runs of specimens from each QC lot and calculated mean values and standard deviations from these data. Data values outside the 99% confidence interval for each QC lot were not included in the computations. We could not include qualitative data, data submitted as inequalities or ranges, data submitted in unidentified units, or data from more than five analytic runs per specimen lot per participant. Some participants submitted results in units other than those requested on the data-report forms. To ensure that all results are appropriately entered in the CDC database, participants should convert their results to the requested units before entering them on the data-report forms.

The reported QC data are summarized in tables on pages 4-25, which show the analyte by series of QC lots, the number of measurements (N), the mean values, and the standard deviations (SD) by kit or analytic method. In addition, we used a weighted linear regression analysis to examine the comparability by method of reported versus enriched concentrations. Results of the linear regression analyses are summarized in the tables on pages 4-25.

CDC/APHL

Direct inquiries to:
Centers for Disease Control and Prevention (CDC)
4770 Buford Highway, NE, MS/F43
Atlanta, GA 30341-3724

This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

Phone : 770-488-4582
FAX: 770-488-4255
E-mail: CBell@cdc.gov

Editor :
Production:

Carol Bell
Sarah Brown
Connie Singleton



DISCUSSION

The enriched values of the QC specimen lots, shown in the tables for each lot, do not take into account the endogenous levels of the analytes; however, analytic results indicate that endogenous concentrations are negligible for all analytes except Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines. For Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines, the nonenriched base pools were distributed as the first QC specimen lot in each series so that participants could measure the endogenous Phe, Leu, Met, Tyr, Val, Cit, or acylcarnitine concentration of the series. QC lots 525–528 were enriched with Gal, Phe, Leu, Met, Tyr, Val, and Cit. QC lots 565–568 were enriched with acylcarnitines. All other QC lots were enriched with one analyte per lot. Gal lots 525–528 were enriched with equimolar quantities of simple galactose and galactose-1-phosphate.

The tables, which summarize reported QC results (pages 4–25), provide data for method-related differences in analytic recoveries and method bias. Because we prepared each QC lot series from a single batch of hematocrit-adjusted, nonenriched blood, the endogenous concentration was the same for all specimens in a lot series. We calculated the within-laboratory SD component of the total SD and used the reported QC data from multiple analytic runs for regression analyses. We calculated the Y-intercept and slope listed in each table using all analyte concentrations within a lot series (e.g., lots 511, 512, and 513). Because only three or four concentrations of QC materials are available for each analyte, a bias error in any one pool can markedly influence the slope and intercept. The Y-intercept provides one measure of the endogenous con-

centration level for an analyte. For Phe, Leu, Met, Tyr, Val, Cit, and the acylcarnitines, participants measured the endogenous concentration levels by analyzing the nonenriched QC lots. When endogenous levels were compared for the amino acids and the acylcarnitines, we found them to be similar for all methods per analyte. Ideally, the slope should be 1.0, and most slopes were close to this value, ranging from 0.8 to 1.2 but some were a bit farther away. For example, for one Gal method, the slope was 1.4; for one Leu method, the slope was 1.5; for one C14 method, the slope was 0.68; and for two C5DC methods, the slopes were 0.65 and 0.69. The C5DC methods show the greatest variation in slopes among all analytes. For C5DC, note that for both kit and non-kit users, the calculation of concentrations for the QC lots varied with type of internal standard. Data are not sorted by internal standard type. In a 2003 survey, participants reported using d₉-C5, d₃-C8, d₃-C10, d₃-C12, d₃-C16, or d₆-C5DC as an internal standard for C5DC. These slope deviations may be related to analytic ranges for calibration curves. Because the endogenous concentration was the same for all QC lots within a series, it should not affect the slope of the regression line among methods. Generally, slope values substantially different from 1.0 indicate that a method has an analytic bias.

Each year, with the extensive cooperation of Whatman Inc., we routinely monitor the absorption characteristics of approved filter paper. (Participants may refer to page 6 of the 2005 Newborn Screening Quality Assurance Program summary report* for charts of the serum absorbancies of 21 Grade 903 filter paper lots that CDC monitored.) The following

Whatman Grade 903 filter paper lots were used in the production of QC specimen lots distributed during the first 6 months of 2006: W041 (Lots 501–503, 525–528, 565–568) and W011 (Lots 451–453, 511–513).


* Bell CJ, editor. Newborn Screening Quality Assurance Program: 2005 Annual Summary Report. Atlanta: Centers for Disease Control and Prevention, 2006;23:1-77.

<http://www.cdc.gov/labstandards/nsqap.htm>

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services or the association of Public Health Laboratories.


<http://www.cdc.gov/labstandards/nsqap.htm>

[Home](#) | [About CDC](#) | [Press Room](#) | [A-Z Index](#) | [Contact Us](#)


Department of Health and Human Services
Centers for Disease Control and Prevention

[CDC en Español](#)

Search: [Go](#)



Laboratory Standards

[Home Page](#)


[Cholesterol Reference Method Laboratory Network](#)

[Lipid Standardization Program](#)

[Newborn Screening Quality Assurance Program](#)

[Vitamin A Laboratory - External Quality Assurance](#)

[Contact DLS](#)



Newborn Screening Quality Assurance Program

[Email This Page](#)
[Print This Page](#)

Current Program Reports

Date	Report	Format
January 2006	2005 Annual Summary Report	PDF 1MB
May 2005	Midyear QC Report	PDF 170KB
May 2006	HIV Titration Curve Summary Report	PDF 281KB

[Archived Annual Summary and Midyear QC Reports \(2002 - 2005\)](#)

Cutoff Charts

Date	Report	Format
February 2006	2005 Cutoff Summary by MS/MS Method (Scatter Plots)	PDF 348KB
February 2006	17-OHP Cutoff Values by Method (Bar Graphs)	PDF 17KB

Quarterly Proficiency Testing Reports

Category
Sickle Cell/Hemoglobins
Cystic Fibrosis (IRT/DNA)
Toxoplasma Antibodies
Anti-HIV-1

Conferences

Date(s)	Conference
May 2005	Unsatisfactory Newborn Screening Specimens: Interpretations, Studies and Current Trends Web Conference
Jan/Feb 2004	Tandem Mass Spectrometry QC/QA for Newborn Screening Web Conference

Downloads

File	Format
Request Participation Form	PDF 13KB

Note: To view a PDF you must have the [Adobe Acrobat Reader®](#) software installed on your computer.

[▲ Back To Top](#)

Last Reviewed: May 26, 2006

[Division of Laboratory Sciences](#)
[Environmental Health Topics](#)

NSQAP Resources

[Program Background](#)

[Program Overview](#)

[Archived Program Reports](#)

[Program Services](#)

[Archived Web Conferences](#)


[Request Participation Form](#)
PDF 13KB


[Applications of Bloodspot Technology](#)

[Partners and Related Links](#)

[Home](#) | [Policies and Regulations](#) | [Disclaimer](#) | [e-Government](#) | [FOIA](#) | [Contact Us](#)

SAFER • HEALTHIER • PEOPLE™
Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA 30333, U.S.A.
Tel: (404) 639-3311 / Public Inquiries: (404) 639-3534 / (800) 311-3435


FIRSTGOV
Your First Click to the U.S. Government


Department of Health and Human Services

2006 Quality Control Data
Summaries of Statistical Analyses

THYROXINE ($\mu\text{g T}_4/\text{dL serum}$)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 501 - Enriched 2 $\mu\text{g}/\text{dL}$ serum						
Diagnostic Products	20	3.2	0.6	0.6	1.4	0.9
MP Biomedicals (ICN) RIA	20	2.5	0.5	0.5	1.0	0.9
Neo-Genesis Accuwell	39	2.9	1.0	1.0	1.6	0.7
Delfia	111	2.6	0.3	0.4	1.0	0.8
AutoDelfia	330	2.4	0.4	0.7	0.8	0.8
Other	39	2.5	0.3	0.4	0.3	1.0

Lot 502 - Enriched 7 $\mu\text{g}/\text{dL}$ serum

Diagnostic Products	20	7.8	1.5	1.6	1.4	0.9
MP Biomedicals (ICN) RIA	30	7.7	1.0	2.4	1.0	0.9
Neo-Genesis Accuwell	39	6.9	1.2	1.4	1.6	0.7
Delfia	111	6.9	0.6	0.9	1.0	0.8
AutoDelfia	328	6.6	0.6	0.8	0.8	0.8
Other	38	7.4	0.4	0.5	0.3	1.0

Lot 503 - Enriched 11 $\mu\text{g}/\text{dL}$ serum

Diagnostic Products	19	11.4	1.0	1.0	1.4	0.9
MP Biomedicals (ICN) RIA	30	10.5	1.2	2.1	1.0	0.9
Neo-Genesis Accuwell	39	9.5	1.2	1.5	1.6	0.7
Delfia	112	10.0	1.1	1.6	1.0	0.8
AutoDelfia	332	9.6	1.0	1.3	0.8	0.8
Other	37	11.9	0.6	0.6	0.3	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μ IU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 511 - Enriched 25 μ IU/mL serum						
Diagnostic Products	30	31.0	2.5	4.9	-1.1	1.3
Neo-Genesis Accuwell	30	24.3	3.0	3.0	-0.7	1.0
MP Biomedicals (ICN) IRMA	20	33.8	2.9	3.2	9.3	1.0
MP Biomedicals (ICN) ELISA	18	21.8	2.7	5.3	-2.0	0.9
Delfia	514	27.5	3.4	5.5	-0.5	1.1
AutoDelfia	736	27.9	2.4	3.0	0.5	1.1
Ani Labsystems	48	30.3	3.9	7.8	5.5	1.0
Bio-Rad Quantase	140	34.1	4.5	7.5	-1.1	1.4
TecnoSuma UMELISA	29	25.9	3.1	4.7	-0.1	1.1
Bioclone ELISA	40	34.4	4.2	7.5	0.9	1.3
DiaSorin	30	33.9	3.7	5.9	3.9	1.2
ECLIA	10	22.3	0.8	0.8	-2.0	1.0
In House	89	30.4	3.4	4.9	4.3	1.0
Other	205	31.0	2.6	4.8	1.6	1.2
Lot 512 - Enriched 40 μ IU/mL serum						
Diagnostic Products	30	51.9	3.9	4.6	-1.1	1.3
Neo-Genesis Accuwell	29	36.6	5.1	5.1	-0.7	1.0
MP Biomedicals (ICN) IRMA	20	48.8	3.3	3.5	9.3	1.0
MP Biomedicals (ICN) ELISA	22	30.0	5.3	8.3	-2.0	0.9
Delfia	511	42.0	4.7	7.0	-0.5	1.1
AutoDelfia	756	42.4	3.8	6.1	0.5	1.1
Ani Labsystems	49	48.0	4.3	10.4	5.5	1.0
Bio-Rad Quantase	139	53.5	6.2	10.9	-1.1	1.4
TecnoSuma UMELISA	29	44.7	7.6	8.2	-0.1	1.1
Bioclone ELISA	40	54.9	5.8	11.2	0.9	1.3
DiaSorin	29	48.8	5.4	7.9	3.9	1.2
ECLIA	10	36.3	1.6	1.6	-2.0	1.0
In House	89	45.7	4.4	6.2	4.3	1.0
Other	209	47.8	4.0	7.2	1.6	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

THYROID-STIMULATING HORMONE (μ IU TSH/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 513 - Enriched 80 μ IU/mL serum						
Diagnostic Products	30	103.2	9.4	12.5	-1.1	1.3
Neo-Genesis Accuwell	29	76.9	9.0	9.1	-0.7	1.0
MP Biomedicals (ICN) IRMA	19	88.0	6.4	6.4	9.3	1.0
MP Biomedicals (ICN) ELISA	20	67.8	9.3	13.5	-2.0	0.9
Delfia	489	86.8	8.9	13.0	-0.5	1.1
AutoDelfia	736	86.3	6.9	8.7	0.5	1.1
Ani Labsystems	50	87.6	7.5	12.0	5.5	1.0
Bio-Rad Quantase	130	109.9	11.5	23.3	-1.1	1.4
TecnoSuma UMEELISA	29	86.0	10.8	12.8	-0.1	1.1
Bioclone ELISA	40	108.5	13.5	23.6	0.9	1.3
DiaSorin	27	97.1	10.6	11.5	3.9	1.2
ECLIA	10	75.2	2.3	2.3	-2.0	1.0
In House	90	87.5	5.5	11.9	4.3	1.0
Other	205	94.8	6.2	15.3	1.6	1.2

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

17 α -HYDROXYPROGESTERONE (ng 17-OHP/mL serum)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 451 - Enriched 25 ng/mL serum						
MP Biomedicals (ICN) RIA	20	27.2	2.9	2.9	1.9	1.0
Neo-Genesis Accuwell	30	26.0	5.2	5.2	3.2	1.0
Delfia	154	29.8	3.9	5.0	2.2	1.1
AutoDelfia	473	30.8	3.4	4.4	-0.4	1.2
Bio-Rad Quantase	30	28.6	5.8	5.9	3.8	1.0
Bayer Medical	20	26.1	2.2	2.2	-0.8	1.1
In house	19	23.3	3.1	3.7	1.2	0.9
Other	20	29.1	4.0	5.4	4.7	1.0
Lot 452 - Enriched 50 ng/mL serum						
MP Biomedicals (ICN) RIA	20	54.1	4.7	6.1	1.9	1.0
Neo-Genesis Accuwell	30	54.1	10.8	11.1	3.2	1.0
Delfia	157	58.7	6.9	9.6	2.2	1.1
AutoDelfia	463	62.1	6.5	7.9	-0.4	1.2
Bio-Rad Quantase	30	56.0	9.7	12.4	3.8	1.0
Bayer Medical	20	51.4	4.8	4.8	-0.8	1.1
In house	20	46.6	4.1	4.1	1.2	0.9
Other	30	53.3	7.1	9.2	4.7	1.0
Lot 453 - Enriched 100 ng/mL serum						
MP Biomedicals (ICN) RIA	20	104.7	12.1	12.9	1.9	1.0
Neo-Genesis Accuwell	28	99.7	14.6	15.1	3.2	1.0
Delfia	157	114.0	13.2	18.1	2.2	1.1
AutoDelfia	469	124.4	11.6	15.7	-0.4	1.2
Bio-Rad Quantase	29	105.6	11.7	12.3	3.8	1.0
Bayer Medical	20	105.2	13.5	13.7	-0.8	1.1
In house	20	91.0	9.6	11.1	1.2	0.9
Other	30	102.1	19.5	32.7	4.7	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

TOTAL GALACTOSE (mg Gal/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Enriched 5 mg/dL whole blood						
Fluorometric Manual	136	5.4	0.6	0.9	-0.4	1.1
Bioassay	10	3.2	0.4	0.4	-0.3	0.7
Colorimetric	68	5.9	0.9	2.3	-1.0	1.2
PerkinElmer Neonatal Kit	12	4.6	0.7	0.9	-0.8	1.1
Neo-Genesis Accuwell	30	5.9	0.5	0.6	-0.3	1.0
Bio-Rad Quantase	193	5.7	0.9	1.5	-1.6	1.3
MP Biomedicals (ICN) Enzyme	40	8.9	0.9	1.5	2.1	1.4
Interscientific Enzyme	10	6.5	0.3	0.3	1.3	1.0
Astoria-Pacific	86	8.0	0.9	1.2	2.0	1.1
Other	90	5.2	1.1	1.7	0.1	1.0

Lot 526 - Enriched 10 mg/dL whole blood

Fluorometric Manual	135	10.5	1.1	1.4	-0.4	1.1
Bioassay	10	6.9	0.7	0.7	-0.3	0.7
Colorimetric	67	11.5	1.8	3.0	-1.0	1.2
PerkinElmer Neonatal Kit	12	11.1	1.2	1.2	-0.8	1.1
Neo-Genesis Accuwell	30	10.2	1.1	1.2	-0.3	1.0
Bio-Rad Quantase	187	11.8	1.6	2.5	-1.6	1.3
MP Biomedicals (ICN) Enzyme	40	16.0	1.2	3.4	2.1	1.4
Interscientific Enzyme	10	11.8	0.5	0.5	1.3	1.0
Astoria-Pacific	85	13.3	1.1	1.6	2.0	1.1
Other	90	9.9	1.8	2.7	0.1	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

TOTAL GALACTOSE (mg Gal/dL whole blood)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 527 - Enriched 15 mg/dL whole blood						
Fluorometric Manual	135	15.7	1.2	1.8	-0.4	1.1
Bioassay	10	9.8	0.9	0.9	-0.3	0.7
Colorimetric	68	16.2	2.5	4.9	-1.0	1.2
PerkinElmer Neonatal Kit	11	16.3	0.8	0.8	-0.8	1.1
Neo-Genesis Accuwell	30	13.7	2.2	2.2	-0.3	1.0
Bio-Rad Quantase	199	16.0	1.8	4.3	-1.6	1.3
MP Biomedicals (ICN) Enzyme	40	24.1	1.7	2.6	2.1	1.4
Interscientific Enzyme	10	16.3	0.3	0.3	1.3	1.0
Astoria-Pacific	88	18.5	1.4	1.9	2.0	1.1
Other	90	14.3	2.2	5.2	0.1	1.0

Lot 528 - Enriched 30 mg/dL whole blood

Fluorometric Manual	134	32.5	2.0	3.6	-0.4	1.1
Bioassay	10	20.7	0.6	0.6	-0.3	0.7
Colorimetric	68	36.5	4.9	7.1	-1.0	1.2
PerkinElmer Neonatal Kit	12	33.5	2.3	7.6	-0.8	1.1
Neo-Genesis Accuwell	30	31.8	3.7	6.1	-0.3	1.0
Bio-Rad Quantase	191	38.0	4.1	7.2	-1.6	1.3
MP Biomedicals (ICN) Enzyme	30	44.3	4.1	4.1	2.1	1.4
Interscientific Enzyme	10	32.3	1.7	1.7	1.3	1.0
Astoria-Pacific	87	36.1	3.4	4.1	2.0	1.1
Other	90	29.7	4.1	9.8	0.1	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

PHENYLALANINE (mg Phe/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	20	1.5	0.2	0.4	1.3	1.1
Fluorometric Manual	89	2.1	0.2	0.4	2.0	1.0
Fluor Cont Flo, In house	36	2.2	0.2	0.4	2.1	1.2
Fluor cont Flo, Kit	69	1.8	0.2	0.3	1.8	1.1
Colorimetric	78	1.9	0.3	0.4	1.8	1.3
PerkinElmer Neonatal Kit	299	1.5	0.2	0.3	1.5	1.0
Neo-Genesis Accuwell	30	1.9	0.2	0.2	1.4	1.1
Ani Labsystems	50	1.7	0.3	0.7	1.6	1.1
Bio-Rad Quantase	86	1.6	0.2	0.4	1.5	1.1
MP Biomedicals (ICN) Enzyme	10	1.5	0.1	0.1	1.2	0.9
Interscientific Enzyme	40	1.6	0.2	0.2	1.6	1.0
Astoria-Pacific	19	2.8	0.2	0.2	2.7	1.3
Thin-layer Chromotography	10	1.5	0.2	0.2	1.3	1.0
HPLC	50	1.5	0.1	0.2	1.5	1.0
TecnoSuma UMTEST	20	2.5	0.4	1.3	2.2	1.0
Derivatized-MS/MS Non-Kit	640	1.6	0.2	0.3	1.6	1.0
Non-derivatized MS/MS Non-Kit	89	1.8	0.2	0.4	1.7	1.1
Deriv-MS/MS PE NeoGram	177	1.6	0.1	0.2	1.7	0.9
Non-deriv MS/MS PE NeoGram	29	1.7	0.1	0.3	1.6	1.1
Other	40	1.3	0.4	0.8	1.0	1.0
Lot 526 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	30	4.5	0.6	0.7	1.3	1.1
Fluorometric Manual	88	5.2	0.4	0.5	2.0	1.0
Fluor Cont Flo, In house	36	5.5	0.4	1.0	2.1	1.2
Fluor cont Flo, Kit	69	5.0	0.5	0.6	1.8	1.1
Colorimetric	77	5.8	0.4	0.5	1.8	1.3
PerkinElmer Neonatal Kit	298	4.5	0.4	0.6	1.5	1.0
Neo-Genesis Accuwell	30	4.9	0.5	0.5	1.4	1.1
Ani Labsystems	50	4.8	0.4	0.6	1.6	1.1
Bio-Rad Quantase	86	4.7	0.4	0.6	1.5	1.1
MP Biomedicals (ICN) Enzyme	20	4.0	0.6	0.6	1.2	0.9
Interscientific Enzyme	39	4.9	0.4	0.6	1.6	1.0
Astoria-Pacific	19	6.6	0.5	0.5	2.7	1.3
Thin-layer Chromotography	10	3.9	0.3	0.3	1.3	1.0
HPLC	48	4.5	0.3	0.4	1.5	1.0
TecnoSuma UMTEST	20	4.7	1.0	1.0	2.2	1.0
Derivatized-MS/MS Non-Kit	640	4.5	0.4	0.7	1.6	1.0
Non-derivatized MS/MS Non-Kit	88	4.8	0.4	1.1	1.7	1.1
Deriv-MS/MS PE NeoGram	177	4.5	0.4	0.5	1.7	0.9
Non-deriv MS/MS PE NeoGram	30	4.7	0.3	0.4	1.6	1.1
Other	40	4.1	1.0	1.5	1.0	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

PHENYLALANINE (mg Phe/dL whole blood)

- continued -

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 527 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	30	8.2	0.8	1.0	1.3	1.1
Fluorometric Manual	90	9.0	0.6	0.8	2.0	1.0
Fluor Cont Flo, In house	36	10.1	0.6	1.6	2.1	1.2
Fluor cont Flo, Kit	70	9.5	0.7	0.8	1.8	1.1
Colorimetric	77	10.1	0.8	1.1	1.8	1.3
PerkinElmer Neonatal Kit	300	8.1	0.7	1.0	1.5	1.0
Neo-Genesis Accuwell	30	7.6	1.1	1.3	1.4	1.1
Ani Labsystems	47	9.5	0.8	1.3	1.6	1.1
Bio-Rad Quantase	89	8.6	0.9	1.4	1.5	1.1
MP Biomedicals (ICN) Enzyme	19	7.8	0.7	0.8	1.2	0.9
Interscientific Enzyme	39	7.9	0.9	1.2	1.6	1.0
Astoria-Pacific	20	11.9	0.5	1.3	2.7	1.3
Thin-layer Chromotography	10	8.4	0.5	0.5	1.3	1.0
HPLC	50	8.5	0.6	1.2	1.5	1.0
TecnoSuma UMTEST	20	8.7	1.4	1.4	2.2	1.0
Derivatized-MS/MS Non-Kit	638	8.3	0.8	1.4	1.6	1.0
Non-derivatized MS/MS Non-Kit	89	9.3	0.8	2.3	1.7	1.1
Deriv-MS/MS PE NeoGram	178	7.9	0.6	0.9	1.7	0.9
Non-deriv MS/MS PE NeoGram	29	8.5	0.7	0.8	1.6	1.1
Other	40	7.2	1.2	2.1	1.0	1.0
Lot 528 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	30	13.2	1.8	2.9	1.3	1.1
Fluorometric Manual	88	13.4	1.0	1.4	2.0	1.0
Fluor Cont Flo, In house	36	15.0	1.4	2.7	2.1	1.2
Fluor cont Flo, Kit	70	14.0	1.2	1.4	1.8	1.1
Colorimetric	77	16.2	0.9	1.3	1.8	1.3
PerkinElmer Neonatal Kit	304	12.5	1.1	1.6	1.5	1.0
Neo-Genesis Accuwell	29	14.4	0.8	0.8	1.4	1.1
Ani Labsystems	52	13.8	1.6	2.0	1.6	1.1
Bio-Rad Quantase	88	13.5	1.5	2.7	1.5	1.1
MP Biomedicals (ICN) Enzyme	20	11.7	1.0	1.2	1.2	0.9
Interscientific Enzyme	40	13.0	1.2	1.4	1.6	1.0
Astoria-Pacific	20	17.6	0.8	1.9	2.7	1.3
Thin-layer Chromotography	10	12.1	0.4	0.4	1.3	1.0
HPLC	40	12.3	0.9	1.0	1.5	1.0
TecnoSuma UMTEST	19	13.1	1.3	1.7	2.2	1.0
Derivatized-MS/MS Non-Kit	643	12.4	1.1	2.2	1.6	1.0
Non-derivatized MS/MS Non-Kit	88	13.5	1.1	3.4	1.7	1.1
Deriv-MS/MS PE NeoGram	176	11.7	1.1	1.5	1.7	0.9
Non-deriv MS/MS PE NeoGram	30	13.5	0.8	0.8	1.6	1.1
Other	40	13.0	1.6	3.7	1.0	1.0

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

LEUCINE (mg Leu/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Bacterial Inhibition Assays	10	2.5	0.5	0.5	1.8	1.5
Bio-Rad Quantase	20	3.4	0.5	0.5	3.0	1.3
Thin-layer Chromotography	20	2.8	0.4	0.4	2.7	1.0
HPLC	29	2.4	0.2	0.4	2.5	1.0
Derivatized-MS/MS Non-Kit	585	2.8	0.3	0.5	2.6	1.0
Non-derivatized MS/MS Non-Kit	60	3.2	0.3	0.5	3.0	1.0
Deriv-MS/MS PE NeoGram	187	2.8	0.3	0.4	2.7	1.0
Non-deriv MS/MS PE NeoGram	20	3.0	0.2	0.2	2.8	0.8
Other	10	1.0	0.4	0.4	0.9	0.9
Lot 526 - Enriched 3 mg/dL whole blood						
Bacterial Inhibition Assays	9	7.0	0.0	0.0	1.8	1.5
Bio-Rad Quantase	20	6.9	0.8	1.4	3.0	1.3
Thin-layer Chromotography	20	5.4	0.5	0.5	2.7	1.0
HPLC	29	5.6	0.6	0.6	2.5	1.0
Derivatized-MS/MS Non-Kit	586	5.5	0.5	0.9	2.6	1.0
Non-derivatized MS/MS Non-Kit	59	5.6	0.5	0.8	3.0	1.0
Deriv-MS/MS PE NeoGram	193	5.6	0.5	0.7	2.7	1.0
Non-deriv MS/MS PE NeoGram	20	5.1	0.5	0.5	2.8	0.8
Other	10	3.3	0.8	0.8	0.9	0.9
Lot 527 - Enriched 7 mg/dL whole blood						
Bacterial Inhibition Assays	10	9.0	0.0	0.0	1.8	1.5
Bio-Rad Quantase	20	10.5	1.7	3.2	3.0	1.3
Thin-layer Chromotography	20	9.4	0.5	1.0	2.7	1.0
HPLC	30	9.9	0.7	1.6	2.5	1.0
Derivatized-MS/MS Non-Kit	591	9.7	0.9	1.6	2.6	1.0
Non-derivatized MS/MS Non-Kit	60	9.8	0.9	1.6	3.0	1.0
Deriv-MS/MS PE NeoGram	190	9.3	0.8	1.1	2.7	1.0
Non-deriv MS/MS PE NeoGram	20	8.3	0.9	1.0	2.8	0.8
Other	10	6.9	1.2	1.2	0.9	0.9
Lot 528 - Enriched 11 mg/dL whole blood						
Bacterial Inhibition Assays	10	20.0	0.0	0.0	1.8	1.5
Bio-Rad Quantase	18	17.6	1.3	5.1	3.0	1.3
Thin-layer Chromotography	20	13.3	0.6	1.3	2.7	1.0
HPLC	20	13.3	1.6	1.6	2.5	1.0
Derivatized-MS/MS Non-Kit	585	14.0	1.3	2.4	2.6	1.0
Non-derivatized MS/MS Non-Kit	60	13.5	1.6	2.8	3.0	1.0
Deriv-MS/MS PE NeoGram	192	13.4	1.1	2.0	2.7	1.0
Non-deriv MS/MS PE NeoGram	19	11.9	0.7	1.2	2.8	0.8
Other	10	10.3	1.9	1.9	0.9	0.9

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

METHIONINE (mg Met/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromotography	10	0.0	0.0	0.0	0.1	0.7
HPLC	30	0.3	0.1	0.1	0.2	0.8
Derivatized-MS/MS Non-Kit	584	0.4	0.1	0.1	0.4	0.8
Non-derivatized MS/MS Non-Kit	57	0.4	0.1	0.4	0.4	0.8
Deriv-MS/MS PE NeoGram	182	0.5	0.1	0.1	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	0.4	0.1	0.1	0.3	0.7
Other	10	0.5	0.3	0.3	0.6	0.5
Lot 526 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromotography	10	1.0	0.0	0.0	0.1	0.7
HPLC	29	1.0	0.2	0.2	0.2	0.8
Derivatized-MS/MS Non-Kit	585	1.2	0.1	0.2	0.4	0.8
Non-derivatized MS/MS Non-Kit	59	1.2	0.3	0.4	0.4	0.8
Deriv-MS/MS PE NeoGram	182	1.3	0.1	0.2	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	1.0	0.1	0.2	0.3	0.7
Other	10	1.2	0.4	0.4	0.6	0.5
Lot 527 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromotography	10	2.3	0.5	0.5	0.1	0.7
HPLC	30	2.6	0.2	0.4	0.2	0.8
Derivatized-MS/MS Non-Kit	581	2.9	0.3	0.4	0.4	0.8
Non-derivatized MS/MS Non-Kit	60	2.8	0.4	0.6	0.4	0.8
Deriv-MS/MS PE NeoGram	182	2.9	0.3	0.4	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	2.4	0.4	0.5	0.3	0.7
Other	10	2.1	0.4	0.4	0.6	0.5
Lot 528 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromotography	10	4.4	0.5	0.5	0.1	0.7
HPLC	20	5.0	0.5	0.5	0.2	0.8
Derivatized-MS/MS Non-Kit	584	5.4	0.5	0.9	0.4	0.8
Non-derivatized MS/MS Non-Kit	59	5.2	0.8	0.9	0.4	0.8
Deriv-MS/MS PE NeoGram	185	5.6	0.6	0.9	0.4	0.9
Non-deriv MS/MS PE NeoGram	20	4.5	0.4	0.6	0.3	0.7
Other	10	3.6	0.8	0.8	0.6	0.5

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

TYROSINE (mg Tyr/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Fluorometric Manual	10	2.3	0.3	0.3	2.1	1.1
Thin-Layer Chromotography	10	1.0	0.2	0.2	0.9	0.9
HPLC	40	1.2	0.1	0.2	1.3	0.9
Derivatized-MS/MS Non-Kit	601	1.2	0.1	0.2	1.2	0.9
Non-derivatized MS/MS Non-Kit	78	1.4	0.2	0.4	1.3	1.0
Deriv-MS/MS PE NeoGram	187	1.2	0.1	0.2	1.2	0.9
Non-deriv MS/MS PE NeoGram	22	1.2	0.1	0.2	1.1	0.7
Other	10	1.3	0.5	0.5	1.3	0.6
Lot 526 - Enriched 1 mg/dL whole blood						
Fluorometric Manual	10	3.3	0.5	0.5	2.1	1.1
Thin-Layer Chromotography	10	1.8	0.2	0.2	0.9	0.9
HPLC	40	2.2	0.2	0.5	1.3	0.9
Derivatized-MS/MS Non-Kit	601	2.0	0.2	0.3	1.2	0.9
Non-derivatized MS/MS Non-Kit	79	2.1	0.3	0.6	1.3	1.0
Deriv-MS/MS PE NeoGram	190	2.1	0.2	0.3	1.2	0.9
Non-deriv MS/MS PE NeoGram	22	1.8	0.1	0.2	1.1	0.7
Other	10	1.8	0.7	0.7	1.3	0.6
Lot 527 - Enriched 3 mg/dL whole blood						
Fluorometric Manual	10	5.0	0.5	0.5	2.1	1.1
Thin-Layer Chromotography	10	3.2	0.4	0.4	0.9	0.9
HPLC	38	4.0	0.2	0.9	1.3	0.9
Derivatized-MS/MS Non-Kit	609	3.8	0.4	0.7	1.2	0.9
Non-derivatized MS/MS Non-Kit	80	4.2	0.5	1.0	1.3	1.0
Deriv-MS/MS PE NeoGram	192	3.8	0.4	0.6	1.2	0.9
Non-deriv MS/MS PE NeoGram	22	3.3	0.3	0.3	1.1	0.7
Other	10	3.2	0.7	0.7	1.3	0.6
Lot 528 - Enriched 8 mg/dL whole blood						
Fluorometric Manual	10	10.9	0.9	0.9	2.1	1.1
Thin-Layer Chromotography	10	7.8	0.9	0.9	0.9	0.9
HPLC	30	8.1	0.6	1.4	1.3	0.9
Derivatized-MS/MS Non-Kit	608	8.3	0.8	1.6	1.2	0.9
Non-derivatized MS/MS Non-Kit	80	8.9	1.1	2.3	1.3	1.0
Deriv-MS/MS PE NeoGram	188	8.4	0.9	1.2	1.2	0.9
Non-deriv MS/MS PE NeoGram	22	7.0	0.4	0.4	1.1	0.7
Other	10	5.8	1.3	1.3	1.3	0.6

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

VALINE (mg Val/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromotography	20	1.3	0.2	0.4	1.3	0.7
HPLC	30	2.2	0.2	0.3	2.4	0.9
Derivatized-MS/MS Non-Kit	511	2.0	0.2	0.5	1.9	0.8
Non-derivatized MS/MS Non-Kit	49	1.8	0.1	0.4	1.8	0.7
Deriv-MS/MS PE NeoGram	164	2.1	0.3	0.5	2.0	0.8
Non-deriv MS/MS PE NeoGram	20	2.2	0.1	0.3	2.1	0.7
Other	10	2.4	0.6	0.6	2.7	0.8
Lot 526 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromotography	20	2.2	0.4	0.4	1.3	0.7
HPLC	30	3.3	0.3	0.5	2.4	0.9
Derivatized-MS/MS Non-Kit	516	2.7	0.3	0.7	1.9	0.8
Non-derivatized MS/MS Non-Kit	49	2.4	0.2	0.5	1.8	0.7
Deriv-MS/MS PE NeoGram	166	2.8	0.3	0.7	2.0	0.8
Non-deriv MS/MS PE NeoGram	20	2.7	0.2	0.3	2.1	0.7
Other	10	3.8	1.0	1.0	2.7	0.8
Lot 527 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromotography	20	3.2	0.4	0.6	1.3	0.7
HPLC	30	5.2	0.5	1.1	2.4	0.9
Derivatized-MS/MS Non-Kit	514	4.3	0.5	1.0	1.9	0.8
Non-derivatized MS/MS Non-Kit	50	3.9	0.5	1.0	1.8	0.7
Deriv-MS/MS PE NeoGram	163	4.4	0.5	1.0	2.0	0.8
Non-deriv MS/MS PE NeoGram	20	4.0	0.5	0.7	2.1	0.7
Other	10	5.1	0.8	0.8	2.7	0.8
Lot 528 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromotography	20	5.6	0.5	1.8	1.3	0.7
HPLC	20	7.5	0.7	1.0	2.4	0.9
Derivatized-MS/MS Non-Kit	511	6.7	0.8	1.6	1.9	0.8
Non-derivatized MS/MS Non-Kit	48	5.8	0.6	1.3	1.8	0.7
Deriv-MS/MS PE NeoGram	164	6.9	0.9	1.7	2.0	0.8
Non-deriv MS/MS PE NeoGram	20	6.3	0.5	0.8	2.1	0.7
Other	10	7.5	1.4	1.4	2.7	0.8

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

CITRULLINE (mg Cit/dL whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 525 - Nonenriched 0 mg/dL whole blood						
Thin-Layer Chromotography	12	0.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	539	0.4	0.1	0.1	0.4	0.7
Non-derivatized MS/MS Non-Kit	49	0.4	0.1	0.1	0.4	0.7
Deriv-MS/MS PE NeoGram	178	0.5	0.0	0.1	0.6	0.9
Non-deriv MS/MS PE NeoGram	20	0.8	0.2	0.2	0.7	1.0
Other	10	0.7	0.3	0.3	0.7	0.7
Lot 526 - Enriched 1 mg/dL whole blood						
Thin-Layer Chromotography	12	1.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	543	1.1	0.1	0.3	0.4	0.7
Non-derivatized MS/MS Non-Kit	50	1.1	0.1	0.2	0.4	0.7
Deriv-MS/MS PE NeoGram	180	1.5	0.1	0.2	0.6	0.9
Non-deriv MS/MS PE NeoGram	20	1.7	0.3	0.3	0.7	1.0
Other	9	1.4	0.4	0.4	0.7	0.7
Lot 527 - Enriched 3 mg/dL whole blood						
Thin-Layer Chromotography	12	2.0	0.0	0.0	0.2	0.6
Derivatized-MS/MS Non-Kit	550	2.4	0.3	0.7	0.4	0.7
Non-derivatized MS/MS Non-Kit	50	2.5	0.3	0.5	0.4	0.7
Deriv-MS/MS PE NeoGram	175	3.2	0.2	0.5	0.6	0.9
Non-deriv MS/MS PE NeoGram	20	3.6	0.6	0.6	0.7	1.0
Other	10	2.9	0.8	0.8	0.7	0.7
Lot 528 - Enriched 6 mg/dL whole blood						
Thin-Layer Chromotography	12	3.8	0.4	0.4	0.2	0.6
Derivatized-MS/MS Non-Kit	546	4.4	0.5	1.3	0.4	0.7
Non-derivatized MS/MS Non-Kit	50	4.5	0.6	1.0	0.4	0.7
Deriv-MS/MS PE NeoGram	175	6.0	0.4	1.0	0.6	0.9
Non-deriv MS/MS PE NeoGram	19	6.5	0.8	0.8	0.7	1.0
Other	10	4.9	1.5	1.5	0.7	0.7

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

PROPIONYLCARNITINE ($\mu\text{mol C3/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	660	1.56	0.22	0.29	1.56	1.14
Non-derivatized MS/MS Non-Kit	49	1.50	0.18	0.32	1.33	1.20
Deriv-MS/MS PE NeoGram	177	1.37	0.14	0.22	1.25	1.05
Non-deriv MS/MS PE NeoGram	48	1.31	0.24	0.31	1.27	1.02
Lot 566 - Enriched 3 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	676	4.94	0.72	0.95	1.56	1.14
Non-derivatized MS/MS Non-Kit	50	4.88	0.60	1.03	1.33	1.20
Deriv-MS/MS PE NeoGram	180	4.37	0.35	0.69	1.25	1.05
Non-deriv MS/MS PE NeoGram	50	4.13	0.59	0.84	1.27	1.02
Lot 567 - Enriched 7.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	666	10.13	1.17	1.83	1.56	1.14
Non-derivatized MS/MS Non-Kit	50	9.96	1.24	1.83	1.33	1.20
Deriv-MS/MS PE NeoGram	177	8.90	0.73	1.28	1.25	1.05
Non-deriv MS/MS PE NeoGram	51	9.23	1.19	1.35	1.27	1.02
Lot 568 - Enriched 12 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	660	15.15	1.82	2.91	1.56	1.14
Non-derivatized MS/MS Non-Kit	50	15.93	2.05	3.77	1.33	1.20
Deriv-MS/MS PE NeoGram	177	14.04	1.05	2.15	1.25	1.05
Non-deriv MS/MS PE NeoGram	47	13.41	1.72	2.08	1.27	1.02

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

BUTYRYLCARNITINE ($\mu\text{mol C4/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	639	0.20	0.05	0.08	0.19	0.97
Non-derivatized MS/MS Non-Kit	49	0.20	0.06	0.10	0.17	0.88
Deriv-MS/MS PE NeoGram	180	0.21	0.07	0.08	0.16	0.84
Non-deriv MS/MS PE NeoGram	48	0.18	0.07	0.08	0.19	0.82
Lot 566 - Enriched 1 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	641	1.17	0.16	0.23	0.19	0.97
Non-derivatized MS/MS Non-Kit	50	1.04	0.14	0.23	0.17	0.88
Deriv-MS/MS PE NeoGram	175	1.00	0.19	0.24	0.19	0.84
Non-deriv MS/MS PE NeoGram	48	1.01	0.21	0.21	0.19	0.82
Lot 567 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	639	2.62	0.31	0.43	0.19	0.97
Non-derivatized MS/MS Non-Kit	50	2.35	0.25	0.47	0.17	0.88
Deriv-MS/MS PE NeoGram	178	2.17	0.37	0.41	0.16	0.84
Non-deriv MS/MS PE NeoGram	49	2.25	0.49	0.49	0.19	0.82
Lot 568 - Enriched 5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	645	5.07	0.55	0.83	0.19	0.97
Non-derivatized MS/MS Non-Kit	50	4.61	0.50	1.20	0.17	0.88
Deriv-MS/MS PE NeoGram	176	4.40	0.68	0.78	0.16	0.84
Non-deriv MS/MS PE NeoGram	48	4.30	0.61	0.64	0.19	0.82

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

ISOVALERYLCARNITINE ($\mu\text{mol C5/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	662	0.16	0.04	0.06	0.13	1.02
Non-derivatized MS/MS Non-Kit	50	0.14	0.03	0.05	0.10	0.99
Deriv-MS/MS PE NeoGram	179	0.16	0.05	0.05	0.13	0.94
Non-deriv MS/MS PE NeoGram	40	0.13	0.05	0.05	0.13	0.81
Lot 566 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	655	0.62	0.08	0.13	0.13	1.02
Non-derivatized MS/MS Non-Kit	50	0.57	0.08	0.10	0.10	0.99
Deriv-MS/MS PE NeoGram	177	0.58	0.11	0.13	0.13	0.94
Non-deriv MS/MS PE NeoGram	40	0.51	0.12	0.15	0.13	0.81
Lot 567 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	645	1.66	0.20	0.31	0.13	1.02
Non-derivatized MS/MS Non-Kit	50	1.57	0.12	0.19	0.10	0.99
Deriv-MS/MS PE NeoGram	179	1.50	0.24	0.29	0.13	0.94
Non-deriv MS/MS PE NeoGram	39	1.39	0.25	0.25	0.13	0.81
Lot 568 - Enriched 3 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	642	3.21	0.37	0.61	0.13	1.02
Non-derivatized MS/MS Non-Kit	49	3.09	0.30	0.39	0.10	0.99
Deriv-MS/MS PE NeoGram	176	2.97	0.40	0.47	0.13	0.94
Non-deriv MS/MS PE NeoGram	39	2.54	0.38	0.41	0.13	0.81

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

GLUTARYLCARNITINE ($\mu\text{mol C5DC/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - CDC Assayed 0.07 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	640	0.05	0.02	0.03	0.00	0.69
Non-derivatized MS/MS Non-Kit	46	0.05	0.02	0.05	0.00	0.65
Deriv-MS/MS PE NeoGram	172	0.07	0.02	0.02	0.00	1.03
Non-deriv MS/MS PE NeoGram	39	0.21	0.07	0.09	0.10	1.71

Lot 566 - CDC Assayed 0.10 $\mu\text{mol/L}$ whole blood

Derivatized-MS/MS Non-Kit	630	0.07	0.02	0.05	0.00	0.69
Non-derivatized MS/MS Non-Kit	45	0.06	0.02	0.05	0.00	0.65
Deriv-MS/MS PE NeoGram	176	0.10	0.03	0.04	0.00	1.03
Non-deriv MS/MS PE NeoGram	39	0.24	0.07	0.09	0.10	1.71

Lot 567 - CDC Assayed 0.50 $\mu\text{mol/L}$ whole blood

Derivatized-MS/MS Non-Kit	637	0.36	0.09	0.14	0.00	0.69
Non-derivatized MS/MS Non-Kit	46	0.32	0.04	0.27	0.00	0.65
Deriv-MS/MS PE NeoGram	179	0.52	0.10	0.20	0.00	1.03
Non-deriv MS/MS PE NeoGram	39	1.00	0.19	0.19	0.10	1.71

Lot 568 - CDC Assayed 0.98 $\mu\text{mol/L}$ whole blood

Derivatized-MS/MS Non-Kit	630	0.68	0.14	0.25	0.00	0.69
Non-derivatized MS/MS Non-Kit	46	0.63	0.08	0.54	0.00	0.65
Deriv-MS/MS PE NeoGram	176	1.00	0.12	0.38	0.00	1.03
Non-deriv MS/MS PE NeoGram	38	1.74	0.20	0.22	0.10	1.71

Note that for both kit and non-kit users, the calculation of concentrations for the quality control lots varied with type of internal standard. Data are not sorted by internal standard type. In a 2003 survey, participants reported using $d_9\text{-C5}$, $d_3\text{-C8}$, $d_3\text{-C10}$, $d_3\text{-C12}$, $d_3\text{-C16}$, or $d_6\text{-C5DC}$ as an internal standard for C5DC.

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus CDC assayed concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

HEXANOYLCARNITINE ($\mu\text{mol C6/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	663	0.06	0.02	0.04	0.04	0.94
Non-derivatized MS/MS Non-Kit	40	0.07	0.02	0.05	0.05	0.94
Deriv-MS/MS PE NeoGram	172	0.06	0.03	0.04	0.05	0.86
Non-deriv MS/MS PE NeoGram	39	0.04	0.03	0.04	0.02	0.88
Lot 566 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	665	0.49	0.08	0.13	0.04	0.94
Non-derivatized MS/MS Non-Kit	40	0.50	0.06	0.11	0.05	0.94
Deriv-MS/MS PE NeoGram	178	0.48	0.10	0.12	0.05	0.86
Non-deriv MS/MS PE NeoGram	40	0.47	0.10	0.13	0.02	0.88
Lot 567 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	668	0.98	0.15	0.24	0.04	0.94
Non-derivatized MS/MS Non-Kit	39	0.97	0.07	0.14	0.05	0.94
Deriv-MS/MS PE NeoGram	176	0.90	0.16	0.17	0.05	0.86
Non-deriv MS/MS PE NeoGram	40	0.87	0.12	0.13	0.02	0.88
Lot 568 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	663	2.39	0.30	0.53	0.04	0.94
Non-derivatized MS/MS Non-Kit	39	2.40	0.19	0.40	0.05	0.94
Deriv-MS/MS PE NeoGram	176	2.21	0.32	0.39	0.05	0.86
Non-deriv MS/MS PE NeoGram	40	2.23	0.20	0.36	0.02	0.88

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

OCTANOYLCARNITINE ($\mu\text{mol C8/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	679	0.09	0.03	0.05	0.07	1.11
Non-derivatized MS/MS Non-Kit	73	0.08	0.02	0.04	0.05	1.12
Deriv-MS/MS PE NeoGram	184	0.08	0.04	0.04	0.06	0.91
Non-deriv MS/MS PE NeoGram	49	0.07	0.03	0.03	0.06	0.99
Lot 566 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	660	0.60	0.08	0.11	0.07	1.11
Non-derivatized MS/MS Non-Kit	70	0.59	0.06	0.07	0.05	1.12
Deriv-MS/MS PE NeoGram	187	0.50	0.11	0.13	0.06	0.91
Non-deriv MS/MS PE NeoGram	50	0.51	0.07	0.08	0.06	0.99
Lot 567 - Enriched 1.0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	668	1.19	0.16	0.22	0.07	1.11
Non-derivatized MS/MS Non-Kit	73	1.13	0.15	0.18	0.05	1.12
Deriv-MS/MS PE NeoGram	187	0.95	0.19	0.22	0.06	0.91
Non-deriv MS/MS PE NeoGram	48	1.08	0.11	0.12	0.06	0.99
Lot 568 - Enriched 2.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	672	2.84	0.36	0.53	0.07	1.11
Non-derivatized MS/MS Non-Kit	70	2.88	0.26	0.38	0.05	1.12
Deriv-MS/MS PE NeoGram	187	2.35	0.36	0.42	0.06	0.91
Non-deriv MS/MS PE NeoGram	49	2.53	0.21	0.27	0.06	0.99

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

DECANOYLCARNITINE ($\mu\text{mol C10/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	638	0.10	0.03	0.04	0.11	1.27
Non-derivatized MS/MS Non-Kit	38	0.09	0.02	0.03	0.08	1.15
Deriv-MS/MS PE NeoGram	183	0.10	0.04	0.04	0.09	0.88
Non-deriv MS/MS PE NeoGram	49	0.09	0.03	0.04	0.09	0.93
Lot 566 - Enriched 0.25 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	649	0.43	0.07	0.11	0.11	1.27
Non-derivatized MS/MS Non-Kit	40	0.38	0.05	0.06	0.08	1.15
Deriv-MS/MS PE NeoGram	182	0.32	0.08	0.10	0.09	0.88
Non-deriv MS/MS PE NeoGram	48	0.33	0.09	0.11	0.09	0.93
Lot 567 - Enriched 0.75 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	651	1.04	0.16	0.24	0.11	1.27
Non-derivatized MS/MS Non-Kit	39	0.91	0.08	0.13	0.08	1.15
Deriv-MS/MS PE NeoGram	185	0.69	0.12	0.17	0.09	0.88
Non-deriv MS/MS PE NeoGram	50	0.77	0.13	0.13	0.09	0.93
Lot 568 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	642	2.01	0.28	0.48	0.11	1.27
Non-derivatized MS/MS Non-Kit	39	1.82	0.16	0.24	0.08	1.15
Deriv-MS/MS PE NeoGram	183	1.42	0.23	0.33	0.09	0.88
Non-deriv MS/MS PE NeoGram	48	1.49	0.16	0.19	0.09	0.93

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

MYRISTOYLCARNITINE ($\mu\text{mol C14/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	638	0.14	0.04	0.05	0.17	1.02
Non-derivatized MS/MS Non-Kit	29	0.11	0.02	0.03	0.12	1.13
Deriv-MS/MS PE NeoGram	177	0.14	0.04	0.05	0.14	0.91
Non-deriv MS/MS PE NeoGram	49	0.08	0.03	0.03	0.09	0.68
Lot 566 - Enriched 0.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	657	0.65	0.12	0.18	0.17	1.02
Non-derivatized MS/MS Non-Kit	30	0.63	0.06	0.13	0.12	1.13
Deriv-MS/MS PE NeoGram	175	0.58	0.10	0.12	0.14	0.91
Non-deriv MS/MS PE NeoGram	49	0.41	0.06	0.17	0.09	0.68
Lot 567 - Enriched 1.5 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	644	1.82	0.23	0.37	0.17	1.02
Non-derivatized MS/MS Non-Kit	30	1.94	0.20	0.29	0.12	1.13
Deriv-MS/MS PE NeoGram	174	1.55	0.21	0.28	0.14	0.91
Non-deriv MS/MS PE NeoGram	48	1.18	0.12	0.28	0.09	0.68
Lot 568 - Enriched 3 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	649	3.19	0.41	0.65	0.17	1.02
Non-derivatized MS/MS Non-Kit	30	3.44	0.35	0.56	0.12	1.13
Deriv-MS/MS PE NeoGram	172	2.86	0.41	0.50	0.14	0.91
Non-deriv MS/MS PE NeoGram	49	2.09	0.17	0.57	0.09	0.68

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus CDC assayed concentrations and extrapolating the regression to the Y-axis.

2006 Quality Control Data
Summaries of Statistical Analyses

PALMITOYLCARNITINE ($\mu\text{mol C16/L}$ whole blood)

Method	N	Mean	Average Within Lab SD	Total SD	Y- Intercept*	Slope
Lot 565 - Nonenriched 0 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	674	1.40	0.23	0.42	1.42	0.95
Non-derivatized MS/MS Non-Kit	49	1.29	0.12	0.19	1.31	0.94
Deriv-MS/MS PE NeoGram	180	1.22	0.21	0.24	1.18	0.84
Non-deriv MS/MS PE NeoGram	48	1.27	0.19	0.19	1.31	1.00
Lot 566 - Enriched 4 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	658	5.20	0.54	1.01	1.42	0.95
Non-derivatized MS/MS Non-Kit	50	5.09	0.53	0.53	1.31	0.94
Deriv-MS/MS PE NeoGram	177	4.56	0.65	0.76	1.18	0.84
Non-deriv MS/MS PE NeoGram	48	5.28	0.55	0.55	1.31	1.00
Lot 567 - Enriched 8 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	677	9.18	1.08	2.05	1.42	0.95
Non-derivatized MS/MS Non-Kit	49	8.80	0.79	0.82	1.31	0.94
Deriv-MS/MS PE NeoGram	176	7.69	0.93	1.12	1.18	0.84
Non-deriv MS/MS PE NeoGram	49	9.50	1.10	1.25	1.31	1.00
Lot 568 - Enriched 12 $\mu\text{mol/L}$ whole blood						
Derivatized-MS/MS Non-Kit	677	12.76	1.44	2.92	1.42	0.95
Non-derivatized MS/MS Non-Kit	49	12.53	1.15	1.20	1.31	0.94
Deriv-MS/MS PE NeoGram	179	11.33	1.30	1.57	1.18	0.84
Non-deriv MS/MS PE NeoGram	50	13.23	1.40	1.55	1.31	1.00

*Estimated by performing a weighted linear regression analysis of mean reported concentrations versus enriched concentrations and extrapolating the regression to the Y-axis.

NOTES

This **NEWBORN SCREENING QUALITY ASSURANCE PROGRAM** report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC)** and the **Association of Public Health Laboratories**.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
ATLANTA, GA 30341

Director

Julie Louise Gerberding, M.D., M.P.H.

Director

National Center for Environmental Health

Howard Frumkin, M.D., Dr.P.H., M.P.H.

Director

Division of Laboratory Sciences

Eric J. Sampson, Ph.D.

Chief

Newborn Screening Branch

W. Harry Hannon, Ph.D.



Contributors: Barbara W. Adam
Carol Bell
Paul Dantonio
Marie C. Earley, Ph.D.
F. Hugh Gardner
Sherri Hall
L. Omar Henderson, Ph.D.
Sharon Kerr
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Elizabeth McCown
Joanne Mei, Ph.D.
Nancy Meredith
Nishi Patel
Anand Swamy, Ph.D.
Robert Vogt, Ph.D.

Production: Sarah Brown
Felicia Manning
Connie Singleton

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
WASHINGTON, DC 20036-3320

President

Jane Getchell, Dr.P.H.

Chairman, Newborn Screening and Genetics in Public Health Committee

William Becker, D.O., M.P.H.

Chairman, Newborn Screening Quality Assurance Subcommittee

John Sherwin, Ph.D.



INQUIRIES TO:

Carol Bell, Editor • Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program • Mailstop F-43
4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: CBell@cdc.gov